Claim Rejections – 35 USC § 102(e)

Claims 2, 3, 7, 22-24 and 28-35 are reported rejected under 35 USC §102(e) as being anticipated by US Patent No. 6,156,216 (Hossainy et al.). These reported rejections are traversed.

Claims 28-30 and 33 of the reported rejected claims are independent, all other reported rejected claims are dependent from one of these independent claims. If these independent claims do not read on the asserted Hossainy et al. anticipation reference, then the pending rejected dependent claims also do not read on this reference. The conclusion as to dependent claims also reciting allowable subject matter over the asserted Hossainy et al. anticipation reference is premised, at least in part, from 35 USC §112, paragraph 4, where it is directed that a "claim in dependent form shall be construed to incorporate by reference all the limitations of the base claim to which it refers." Thus, each rejected dependent claim includes every limitation recited in its base independent claim. If the independent claims recite limitations that do not read on subject matter disclosed or inherent in the asserted Hossainy et al. anticipation reference, then neither independent claims nor dependent claims are unpatentable under 35 USC §102.

> A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

The rejected independent structure claims, i.e., claims 23, 28 and 30, recite a "composite stent" structure comprising two separate stent structures, one within the other. Therefore, there is an outer stent over an inner stent that comprises the composite stent. The rejected independent method claims, i.e., claims 29 and 33, recite steps for use of a "composite stent structure including an inner stent ..., said inner stent being within an outer stent." These recitations, it is

submitted, are not suggested or inherent from Hossainy et al. disclosures, and, therefore, it is submitted that claimed subject matter distinguishes over Hossainy et al.

Support from the filed specification for the claimed composite stent with an outer stent being over an inner stent include at least the following disclosures that are directed to Figs. 3 and 4 of the filed specification.

> Referring to Figure 3, according to an embodiment of the invention, a composite stent 301 includes an outer bioabsorbable mesh or similar stent element 302 affixed to a fully covered inner self-expanding metal stent (SEMS). Suitable outer bioabsorbable or biodegradable stents are typically made from a bioabsorbable polymer. Polymer structures typically have a higher potential to creep (i.e., experience permanent deformation and fail to return to an original shape and/or size when released) if held in a constrained condition while in the delivery system. The potential for creep in the outer element may increase with temperature elevation such as in sterilization. The fully covered SEMS will self-expand to SEMS as shown in Figure 4 so that the combined structure 401 (including bioabsorbable mesh 402) overcomes any loss in recovered diameter. While some bioabsorbable shape memory polymers may minimize creep, the instant composite stent design simplifies the bioabsorbable material demands. Another advantage of the present invention is that the outer element is not required to support the lumen walls by itself. The inner element may assist the outer element in this respect. Therefore, the outer element may have a lower profile, such as a smaller diameter filament or a flat filament. Through the interaction of the inner element and the outer element the final body lumen diameter, with the stent in place, will have a larger diameter. (Specification paragraph 0038).

Thus the claimed disclosed embodiment is not any composite stent structure but is one having a pair of stents, i.e., an outer stent over an inner stent. It is in this context that the claimed subject matter reads on a composite stent, i.e., a pair of stent devices, each of which is capable of

supporting a bodily orifice. Further, supporting specification disclosures for such combined stent devices include:

> For example, and without limitation, one embodiment of the present invention is directed to a composite stent having an outer stent element that remains for a large period of time in a body lumen and a temporary inner stent element removeably attached to and covering an exposed inner wall surface of the outer element. The outer element may be, for example, a bioabsorbable stent typically constructed of a relatively non-resilient material such that the outer bioabsorbable stent may not be self-expanding and subject to migration within the lumen over time. In contrast, the inner element may be, for example, and without limitation, a removable self-expanding metal stent (SEMS) used to urge and maintain the position of the outer element in the body lumen. The temporary inner SEMS may retain the composite structure (including the underlying inner element) in position until such time as the outer element is appropriately incorporated into the surrounding tissue or some other criteria occurs such that the removal of the SEMS is indicated. The SEMS may then be detached from the outer element and removed from the body lumen. (Specification paragraph 16)

In contradiction to the twin combined stents recited in the pending claims, Hossainy et al. disclose:

> The stent 200 illustratively shown in Fig. 2 includes bands 209 made of a regioselective material that covers only selected discrete regions of the stent. In other embodiments the regioselective material may be applied to stent 200 as strips, as a conformal coating, or as a compression-fitted sleeve. (Col. 3, lines 3-8)
>
> In one embodiment, the material or materials used to form regioselective bands 209 or strips (not shown) are viscoelastic materials having a high creep compliance because such materials are easily expandable and typically exert a gradual and weak

> restoring force that avoids collapsing or substantially deforming an expanded stent over time.
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> * * *
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> In another embodiment, elastic materials may be used provided care is taken to ensure that the stent in its expanded state is capable of sustaining the elastic materials immediate and strong restoring force without collapsing or substantially deforming the expanded stent over time. (Col. 3, lines 44-57)

Hossainy et al. exclusively disclose a single stent with overlying non-stent device(s) and labels the resulting structure a composite stent. Hossainy et al. do not disclose or suggest a combination of an outer stent over an inner stent for any purpose.

It is stated in the Office action, in contradiction to these Hossainy et al. disclosures, that:

> Hossainy et al. discloses a composite stent comprised of an outer stent (209) and an inner stent (100) wherein the outer stent is comprised of a bioabsorbable material (Col. 4, lines 1-30) and exerts a radial force in an outward direction (Col. 3, lines 44-56) .... (Office action, section 4)

Hossainy et al. nowhere disclose or suggest that their "bands 209" are stents capable in any way of supporting a bodily orifice. In fact, for one embodiment they disclose that "bands 209" can be "applied to stent 200 strips, as a conformal coating, or as a compression-fitted sleeve." (Col. 3, lines 3-8). Further, Hossainy et al. nowhere disclose or suggest that their "bands 209" exert "a radial force in an outward direction." What Hossainy et al. instead disclose is that their "bands 209 or strips (not shown) are viscoelastic materials ... easily expandable and typically exert a gradual and weak restoring force that avoids collapsing or substantially deforming an expanded stent over time." (Col. 3, lines 44-49) These are explicit disclosures that Hossainy et al. teach use of "bands 209" having capability to exert radial force inward, i.e. restoring, onto stent 200

and not an outward force directed away from stent 200. Therefore, Hossainy et al. "bands 209" are not stents, and, thus, Hossainy et al. do not teach or suggest any combined stent structure as recited in the pending claims.

It is submitted that the base independent claims and their dependent claims are not anticipated by Hossainy et al. for at least the reasons set forth above.

## CONCLUSION

All pending claims are believed to be in condition for allowance and a notice of the same is requested. Should the Examiner have any questions, requests or suggestions, he is invited to contact the undersigned attorney at the telephone number set out below.

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Respectfully submitted,

By _____

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